

- B11  
cont
53. The process according to claim 48, wherein the step of evaluating the amplified DNA further comprises [the] a step of conducting a hybridization analysis on the amplified DNA.
- 

35 U.S.C. § 112

A) The Examiner states that "[c]laims 1-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention."

It is respectfully pointed out to the Examiner that the amendment to claim 1 which is directed to the analysis of DNA removes the basis for this rejection. Furthermore, as stated in an earlier response, purification and analysis are just steps in the overall process of characterizing DNA.

B) The Examiner states that "[c]laims 1-25, 45-53 are indefinite because the claims do not recite a positive process step which clearly relates back to the preamble."

It is respectfully pointed out to the Examiner that the amendment to claim 1 removes the basis for this rejection.

C) The Examiner states that "[c]laims 4 and 44 are indefinite as it is unclear when the solid support is heated to greater than 60 degrees."

It is respectfully pointed out to the Examiner that the amendment to claim 1 removes the basis for this rejection. The claim as amended has antecedent basis in the

prior claims. Furthermore, as stated in an earlier response the steps are not in order of preference and the heating of the solid support is a modification of claims 1 and 2.

D) The Examiner states that "[c]laims 8-10 are indefinite as it is unclear when the counting of the cells should occur in the method and what purpose the counting entails."

It is respectfully pointed out to the Examiner that the amendment to claims 8-10 removes the basis for this rejection.

E) The Examiner states that "[c]laims 11 and 13 are indefinite over the recitation of "the step of characterizing the remainder of the lysate" because "the remainder", "the step of characterizing" and "the lysate" lacks antecedent basis."

It is respectfully pointed out to the Examiner that the cancellation of claim 11 and the amendment to claim 13 remove the basis for this rejection.

F) The Examiner states that "[c]laims 12 and 14 are indefinite over the recitation of "the step of characterizing the remainder of the biological material" because "the remainder", "the step of characterizing" and "the remainder of the biological material" lacks antecedent basis."

It is respectfully pointed out to the Examiner that the amendments to claims 13 and 14 remove the basis for the rejection based on a lack of antecedence. However, it is pointed out to the Examiner that the term "remainder of the biological material" has antecedent basis in claim 1.

G) The Examiner states that "[c]laims 13 and 14 are indefinite over the recitation of "the step of monitoring impurities" because "the step of monitoring impurities" lacks antecedent basis."

It is respectfully pointed out to the Examiner that the amendments to claims 12, 13, and 14 remove the basis for this rejection.

H) The Examiner states that "[c]laims 15 and 47 are indefinite over the recitation of "the step of quantitating" because "the step of quantitating" lacks antecedent basis."

It is respectfully pointed out to the Examiner that the amendments to claims 15 and 4 remove the basis for this rejection.

I) The Examiner states that "[c]laim 16 is indefinite over the recitation of "the step of adjusting the concentration of DNA" because "the step of adjusting the concentration of DNA" lacks antecedent basis."

It is respectfully pointed out to the Examiner that the amendment to claim 16 removes the basis for this rejection.

J) The Examiner states that "[c]laims 17-23 and 48-53 are indefinite over the recitation of "the step of evaluating" because "the step of evaluating" lacks antecedent basis."

It is respectfully pointed out to the Examiner that the amendments to claims 17-23 and 48-53 remove the basis for this rejection.

K) The Examiner states that "[c]laim 18 is further indefinite over the recitation of "the step of determining the yield" because "the step of determining the yield" lacks antecedent basis.

It is respectfully pointed out to the Examiner that the amendment to claims 18 removes the basis for this rejection.

L) The Examiner states that "[c]laims 19 and 49 are indefinite over the recitation of "the step of determining the size" because "the step of determining the size" lacks antecedent basis.

It is respectfully pointed out to the Examiner that the amendments to claims 19 and 49 remove the basis for this rejection.

M) The Examiner states that "[c]laim 20 is indefinite over the recitation of "the step of determining the purity" because "the step of determining the purity" lacks antecedent basis.

It is respectfully pointed out to the Examiner that the amendment to claim 20 remove the basis for this rejection.

N) The Examiner states that "[c]laims 21 and 50 are indefinite over the recitation of "the step of digesting" because "the step of digesting" lacks antecedent basis."

It is respectfully pointed out to the Examiner that the amendments to claims 21 and 50 remove the basis for this rejection.

O) The Examiner states that "[c]laims 22 and 52 are indefinite over the recitation of "the step of analyzing" because "the step of analyzing" lacks antecedent basis."

It is respectfully pointed out to the Examiner that the amendments to claims 22 and 52 remove the basis for this rejection.

P) The Examiner states that "[c]laims 23 and 53 are indefinite over the recitation of "the step of conducting a hybridization analysis" because "the step of conducting a hybridization analysis" lacks antecedent basis."

It is respectfully pointed out to the Examiner that the amendments to claims 23 and 53 remove the basis for this rejection.

Q) The Examiner states that "[c]laims 26, 28-41, 44, and 46-53 are indefinite over the recitation of step (a) "contacting...with a solid support treated with a lysing matrix" because this phrase makes the claims unclear as to whether the lysing matrix is a liquid solution which is contacted with a solid support whether the lysing matrix is the solid support."

It is respectfully pointed out to the Examiner that the amendments to claims 26, 28-41, 44, and 46-53 remove the basis for this rejection.

R) The Examiner states that "[c]laims 26, 28-41, 44, 46-53 are further indefinite over the recitation of "the lysing reagent" because this term lacks antecedent basis."

It is respectfully pointed out to the Examiner that the amendments to claims 26, 28-41, 44, and 46-53 remove the basis for this rejection.

T) The Examiner states that "[c]laims 24-25 and 45 are indefinite over the recitation of "the step of amplifying" because "the step of amplifying" lacks antecedent basis."

It is respectfully pointed out to the Examiner that the amendments to claims 224-25 and 45 remove the basis for this rejection.

U) The Examiner states that "[c]laims 37-41 are indefinite over the recitation of "the lysing reagent" because "the lysing reagent" lacks antecedent basis."

It is respectfully pointed out to the Examiner that the amendments to claims 37-41 remove the basis for this rejection.

V) The Examiner states that "[c]aim 51 is indefinite over the recitation of "the step of sequencing" because "the step of sequencing" lacks antecedent basis."

It is respectfully pointed out to the Examiner that the amendment to claim 51 removes the basis for this rejection.

#### **35 USC § 102**

**Item 6.** The Examiner states that "[c]laims 1-3, 5-6, 8, 11-21, 23-30, 32-33, 37, 39, 41, 45-51, and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Boom et al (5,234,809)."

It is respectfully pointed out to the Examiner that the amendments to claim 1, 26, 37-41 and the added claims 54, 55, and 56-62 remove the basis for this rejection. The Examiner points out that since "Boom teaches that the GuSCN (i.e. the lysing reagent) is added to the solid support (i.e. the silica beads) prior to addition of biological material,

Boom is inherently teaching a solid support to which a lysing reagent is "bound."

However, the invention of Boom is not the invention claimed by the instant application. Amended claims 1 and 26 are directed to an invention in which the lysing reagent is bound to the solid support and any unbound lysing reagent removed so that no excess lysing reagent is present. Furthermore, added claims 54-55 are directed to an invention in which the lysing reagent is bound to the solid support and dried to the solid support before the biological material is contacted with the solid support. In Boom, however, the lysing reagent (a chaotropic substance) is added in excess to the vessel containing the solid support such that the biological material and solid support form a particulate suspension in the lysing reagent. Boom does not teach removal of any excess lysing reagent prior to the addition of the biological material, nor does it teach drying of the lysing reagent to the solid support.

Furthermore, amended claims 37-41 and added claims 56-60 recite the use of a lysing reagent that is composed of a detergent effective to lyse biological materials sufficiently to release DNA, and a chelating agent that reduces any damage to DNA. Added claims 61-62 further define the lysing reagent as one which is anionic. Therefore, harsh chaotropic substances such as GuSCN are excluded from the scope of the claims.

**Item 7.** The Examiner states that "[c]laims 1-20, 24-33, 37-41, and 44-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Deggerdal (WO 96/18731)."

The Examiner claims that "Deggerdal teaches in the specification that the 'nucleic-acid containing sample may be contacted with the detergent and solid phase which may be added to the sample prior to, simultaneously with, or subsequently to the

detergent . . .” Thus, the Examiner concludes that “Deggerdal is inherently teaching a solid support to which a lysing reagent is ‘bound’ with the recitation that the sample may be added subsequently to the detergent.”

It is respectfully pointed out to the Examiner that Deggerdal teaches a method which comprises simultaneous steps of adding the solid support to the lysing reagent to form a suspension in which the lysing reagent is present in excess. The instant invention, on the other hand, recites the use of a solid support to which the lysing reagent is bound and any excess lysing reagent removed. The instant invention also teaches the use of a solid support to which a lysing reagent is bound and dried before applying the biological material to be lysed. Thus, the instant invention is not the invention of Deggerdal.

### **35 USC § 103**

**Item 9.** The Examiner states that “[c]laims 38 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boom (5, 234,809) in view of Deggerdal (WO 96/18731).”

It is respectfully pointed out to the Examiner that Boom teaches adding a lysing reagent in excess to a solid support. Deggerdal teaches the use of a detergent such as SDS as a lysing reagent. However, it is respectfully pointed out to the Examiner that it would not be prima facie obvious to one of ordinary skill in the art to treat a solid support with a detergent such that the detergent is bound to the solid support and the excess detergent removed. Furthermore, the teachings of Boom and Deggerdal do not collectively teach the treatment of a solid support with a lysing reagent such that the lysing reagent is bound and dried to the solid support.



**Item 10.** The Examiner states that "[c]laims 23 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deggerdal (WO 96/18731) in view of Boom (5,234,809)."

The aforementioned discussions detailing the differences between the current inventions of Boom and Deggerdal overcome this rejection cited by the Examiner.

**Item 11.** The Examiner states that "[c]laims 7, 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boom (5,234,809) in view of Su (5,804,684)."

The aforementioned discussions detailing the differences between the current inventions of Boom and Deggerdal overcome this rejection cited by the Examiner.

**Item 12.** The Examiner states that "[c]laims 42-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boom (5,804,684) or Deggerdal (WO 96/18731) in view of Su (5,804,684)"

The aforementioned discussions detailing the differences between the current inventions of Boom and Deggerdal overcome this rejection cited by the Examiner.

**Item 13.** The Examiner states that "[c]laims 22 and 51-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boom (5,804,684) or Deggerdal (WO 96/18731) in view of Sambrook (Molecular Cloning)."

The aforementioned discussions detailing the differences between the current inventions of Boom and Deggerdal overcome this rejection cited by the Examiner.

**Item 14.** The Examiner states that "[c]laims 33 and 35-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boom (5,804,684) or Deggerdal (WO 96/18731) in view of Arnold (5,599,667)."

The aforementioned discussions detailing the differences between the current inventions of Boom and Deggerdal overcome this rejection cited by the Examiner.

The aforementioned discussions detailing the differences between the current inventions of Boom and Deggerdal overcome this rejection cited by the Examiner.

**Item 15.** The Examiner states that "[c]laim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boom et al (5,234,809) or Deggerdal (WO 96/17831) in view of Arnold (5,599,6667) as applied to claim 33, 35-56 above, and further in view of Hasebe (5,151,345)."

The aforementioned discussions detailing the differences between the current inventions of Boom and Deggerdal overcome this rejection cited by the Examiner.

#### **New Grounds for Objection necessitated by Amendment**

The Examiner states that "[c]laims 4 and 5 are objected to over the recitation 'the process according to claims or 2.' The claim seems to omit the number 1 following the word 'claims.' It is presumed the claim should read 'the process according to claims 1 or 2.' Similarly, it is presumed that Claim 5 omitted the number 2 following the word 'or'."

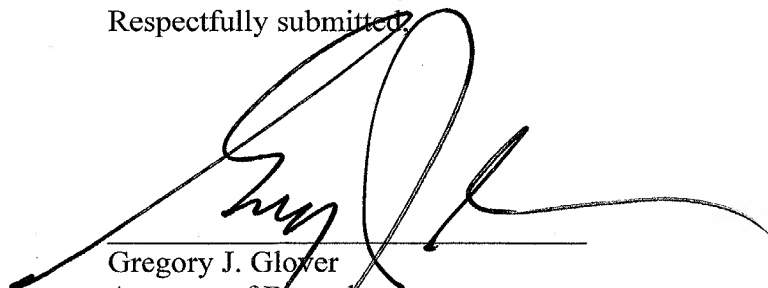
It is respectfully pointed out to the Examiner that claim 5 as amended removes the basis for this rejection.

Reconsideration and withdrawal of the rejections of record is respectfully requested in view of the amendment and remarks contained herein. Claims 1-62 remain pending in this application.

Based on the amendment above, applicant believes all pending claims are in condition for allowance.

If the Examiner believes that a conference would be of value in expediting the prosecution of this application, the Examiner is hereby invited to telephone undersigned counsel to arrange for such a conference.

Respectfully submitted,

A large, stylized handwritten signature in black ink, likely belonging to Gregory J. Glover, is written over a horizontal line.

\_\_\_\_\_  
August 24, 2000

\_\_\_\_\_  
Gregory J. Glover  
Attorney of Record  
Registration No. 34,173  
ROPES & GRAY  
1301 K Street, N.W., Suite 800 East  
Washington, D.C. 20005  
Tel: (202) 626-3900  
Fax: (202) 626-3961